



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

SERIAL NUMBER	FIILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
---------------	--------------	----------------------	---------------------

08/083,590 06/25/93 ARTAVANIS-TSAKONAS S 7326015

WAISH, S EXAMINER

18M2/0317

PENNIE & EDMONDS  
1155 AVENUE OF THE AMERICAS  
NEW YORK, NY 10036-2711

ART UNIT	PAPER NUMBER
----------	--------------

1814

11

DATE MAILED: 03/17/94

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

for restriction purposes only.  
 This application has been examined.  Responsive to communication filed on \_\_\_\_\_  This action is made final.

A shortened statutory period for response to this action is set to expire \_\_\_\_\_ months. 30 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

1.  Notice of References Cited by Examiner, PTO-892.
2.  Notice re Patent Drawing, PTO-948.
3.  Notice of Art Cited by Applicant, PTO-1449.
4.  Notice of Informal Patent Application, Form PTO-152.
5.  Information on How to Effect Drawing Changes, PTO-1474.
6.  \_\_\_\_\_

**Part II SUMMARY OF ACTION**

1.  Claims 1-89 are pending in the application.

Of the above, claims \_\_\_\_\_ are withdrawn from consideration.

2.  Claims \_\_\_\_\_ have been cancelled.

3.  Claims \_\_\_\_\_ are allowed.

4.  Claims \_\_\_\_\_ are rejected.

5.  Claims \_\_\_\_\_ are objected to.

6.  Claims 1-89 are subject to restriction or election requirement.

7.  This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8.  Formal drawings are required in response to this Office action.

9.  The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are  acceptable.  not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10.  The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_ has (have) been  approved by the examiner.  disapproved by the examiner (see explanation).

11.  The proposed drawing correction, filed on \_\_\_\_\_, has been  approved.  disapproved (see explanation).

12.  Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has  been received  not been received  been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.

13.  Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14.  Other \_\_\_\_\_

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

5 I. Claims 1-18, 22, 42-44, 47-52 and 75-83, drawn to pharmaceutical compositions comprising a Notch protein, fragments, chimeras, derivatives or analogs of a Notch protein, methods of treating or preventing malignancy or nervous system disorder, a method of promoting tissue regeneration or repair, and a method of treating a benign dysproliferative disorder, classified in Class 514, subclass 2.

10 II. Claims 19, 20 and 53, drawn to a pharmaceutical composition comprising a derivative or analog of a Delta protein and a method of treating or preventing a malignancy, classified in Class 514, subclass 2.

III. Claims 21 and 54, drawn to a pharmaceutical composition comprising a derivative or analog of a Serrate protein, classified in Class 514, subclass 2.

15 IV. Claims 23-28, 31, 45, 55-58, 63-67 and 84-89, drawn to a pharmaceutical composition comprising a nucleic acid encoding a Notch protein, fragments or chimeras of a Notch protein, a method of treating or preventing malignancy comprising administration of nucleic acid encoding a Notch protein, a method of treating a patient with a tumor, and a pharmaceutical composition comprising an isolated oligonucleotide consisting of at least six nucleotides, classified in Class 514, subclass 44.

20 V. Claims 29 and 59, drawn to a pharmaceutical composition comprising nucleic acid encoding a fragment of a Delta protein, and a method of treating or preventing malignancy comprising administration of nucleic acid encoding a Delta protein, classified in Class 514, subclass 44.

25 VI. Claims 30 and 60, drawn to a pharmaceutical composition comprising nucleic acid encoding a fragment of a Serrate protein, and a method of treating or preventing malignancy comprising administration of nucleic acid encoding a Serrate protein, classified in Class 514, subclass 44.

VII. Claims 32, 33, 41, 61 and 62, drawn to a pharmaceutical composition comprising an antibody and a method of treating or preventing malignancy comprising administration of antibody, classified in Class 424, subclass 85.8.

5 VIII. Claim 46, drawn to a method of treating a disease or disorder in a subject comprising administering a molecule which promotes the function of a Notch protein, classified in Class 514, subclass 1.

IX. Claims 68-74, drawn to a method of diagnosing a disease or disorder, classified in Class 435, subclass 6.

10 Claims 34-40 link inventions I, IV and VII and will be examined if any one of I, IV or VII is elected.

The inventions are distinct, each from the other because of the following reasons:

15 The protein compositions of I, II and III are materially distinct, each from the other, because their chemical structures and biological properties are materially distinct. The methods of I, II and III are materially distinct, each from the other, because they comprise administration of materially distinct compositions and are accordingly practiced with materially distinct process steps.

20 The nucleic acid compositions of IV, V and VI are materially distinct, each from the other, because their chemical structures and biological properties are materially distinct. The methods of IV, V and VI are materially distinct, each from the other, because they comprise administration of materially distinct compositions and are accordingly practiced with materially distinct process steps.

25 The protein compositions of I, II or III are materially distinct from the nucleic acid compositions of IV, V or VI because their chemical structures and biological properties are materially distinct. The methods of I, II or III are materially distinct from the methods of IV, V or VI because they

comprise administration of materially distinct compositions and are accordingly practiced with materially distinct process steps.

5 The antibody compositions VII are materially distinct from the compositions of any of I-VI because their chemical structures and biological properties are materially distinct from those of the proteins or nucleic acids of any of I-VI. The methods of VII are materially distinct from those of any of I-VI because they comprise administration of materially distinct compositions and are accordingly practiced with materially distinct process steps.

10 The methods of VIII are materially distinct as claimed from the methods of any of I-VII because none of the methods of I-VII administer molecules having the activities of the molecules of VIII.

15 The method of IX is materially distinct from the methods of any of I-VIII because the diagnostic method of IX is practiced with materially different process steps from the treatment methods of any one of I-VIII.

20 Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their divergent subject matter, and because the search required for any one of the inventions is not required for any of the other inventions, and because none of the searches required for the various inventions are coextensive, the distinct groups are not coextensive, restriction for examination purposes as indicated is proper.

25 2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Art Unit: 1814

3. A telephone call was made to Attorney Adriane Antler on 11 March 1994 to request an oral election to the above restriction requirement, but did not result in an election being made.

5 Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Walsh whose telephone number is (703) 308-2957.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

15

*Stephen Walsh*  
Stephen Walsh  
Patent Examiner  
Group 1800

20

25

S. Walsh  
March 16, 1994